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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
DEBRA TINLIN and JAMES FRANCES TINLIN, a married couple, Plaintiffs, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFFS' TRIAL BRIEF** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

Plaintiffs respectfully responds to Bard's Trial Brief (Dkt. No. 16944), filed on April 12, 2019. Plaintiffs are submitting a separate brief in response to Bard's other trial brief, concerning non-party fault.

As an initial matter, Plaintiffs note that the Court did not request a trial brief, let alone multiple briefs, on Wisconsin law. The Court has already overseen one bellwether trial in which the claims, most of which overlap with those to be tried here, were governed by Wisconsin law, and made multiple rulings on the issues discussed in Bard's brief. The Court has gone on to make additional rulings in this case, also applying Wisconsin law.

Those rulings speak for themselves, and Plaintiffs object to any attempt to seek reconsideration or modification of those rulings through these briefs. Plaintiffs do not believe additional, lengthy briefs on Wisconsin law will assist the Court, but respond below to the characterizations of Wisconsin law and the record that Bard made in its Trial Brief.

I. WISCONSIN LAW

Wisconsin's product liability law is a statutory scheme, enacted in 2011. *Forsythe v. Indian River Transp. Co.*, 822 N.W.2d 737, *7 n.5 (Wis. Ct. App. 2012) ("We note that the Forsythes filed their strict products liability claim before the effective date of changes to Wisconsin's products liability law enacted by the legislature in January 2011…Thus, we are not faced with the question of whether our analysis would be different under current Wisconsin products liability law.").

Common law is not superseded by the 2011 enacted statutory scheme. If pre-2011 common law rulings are not inconsistent with the statute, they stand. "Wisconsin's 2011 codification of its product liability law generally does not supersede the common law." *Janusz v. Symmetry Med. Inc.*, 256 F. Supp. 3d 995, 1001 (E.D. Wis. 2017).

A. Strict Liability – Design Defect

Strict liability design defect claims are governed by Wis. Stat. 895.047 (2011):

> In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:
>
> (a) …A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe…
>
> (b) That the defective condition rendered the product unreasonably dangerous to persons or property.
>
> (c) That the defective condition existed at the time the product left the control of the manufacturer.
>
> (d) That the product reached the user or consumer without substantial change in the condition in which it was sold.

(e) That the defective condition was a cause of the claimant's damages.

"Unlike negligence, where the focus is upon the defendant's conduct, in strict liability the focus 'is on the dangerousness of the product regardless of the defendant's conduct.' Thus, a defendant may be blameless but strictly liable." *Janusz,* 256 F. Supp. 3d at 1001 citing *Flaminio v. Honda Motor Co.*, 733 F.2d 463, 469 (7th Cir. 1984) (applying Wisconsin law).

This Court synthesized the elements of this claim as follows: "[A] plaintiff claiming strict product liability under Wisconsin law must now show that the product's foreseeable risk of harm could have been reduced or avoided by a reasonable alternative design, and that the failure to adopt the alternative design rendered the product 'not reasonably safe.'" Dkt. No. 12507 (Order on Plaintiff's Motions in Limine Nos. 4 and 5).

1. <u>Plaintiffs Have Proposed Reasonable Alternative Designs.</u>

Plaintiffs have identified reasonable alternative designs for the filter that they contend was defective, and that their expert, Dr. McMeeking, has opined would have helped reduce the risk of failures that led to Ms. Tinlin's injuries. *See* Dkt. No. 17008, at 12-13 (denying motion for summary judgment on design defect claims).[1]

The alternative designs put forth by Plaintiffs do not constitute a "different product," and would not "remove[] a key benefit or design attribute of the alleged defective product." Bard Trial Br., at 3-4. As it has previously, Bard asserts in its trial brief that a permanent filter – one that cannot be percutaneously retrieved – "cannot serve as an alternative design." *Id.* at 4. For this proposition, Bard cites *Oden v. Boston Sci.*

[1] This Court previously held that the alternative designs that Dr. McMeeking were sufficient to satisfy Section 895.047's requirement that a plaintiff identify "an alternative design [that] would have 'reduced' the harm posed by the product," holding that the plaintiffs had "present[ed] evidence that caudal anchors help reduce filter migration, which can lead to other complications like those experienced by Mrs. Hyde (tilt, perforation, and fracture)." Dkt. No. 12007 (Order Granting in Part and Denying in Part Motion for Summary Judgment), at 13. *See also* Dkt. No. 17008, at 13 (listing other alternative designs and alternative features that Dr. McMeeking has opined were available to Bard).

Corp., No. 18-cv-0334, 2018 U.S. Dist. LEXIS 102639, at *12-13 (E.D.N.Y. Jun. 4, 2018). This Court has previously found that the *Oden* case does not support Bard's position, which involves a filter marketed to be both permanent and retrievable.[2] As this Court held, "the Recovery was designed and cleared for permanent use," and the evidentiary record supports that Ms. Tinlin's filter has been implanted as such. Dkt. No. 17008, at 13.[3] Where the filter has been cleared and marketed to be permanent and retrievable, retrievability is not such a "key benefit" (Trial Br. at 4) that to remove it would be akin to "eliminating the product itself," as Wisconsin law requires in challenging an alternative design. *See Godoy v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674, 687 (Wis. 2009) (in case involving lead paint, holding that a product is not a reasonable alternative design "… some ingredients cannot be eliminated from a design without eliminating the product itself.").

Finally, Bard's statement that a "defective product cannot be a reasonable alternative design" is unconnected to the language of Wisconsin's product liability statute. As this Court pointed out, the relevant inquiry is whether the "alternative design would have 'reduced' the harm posed by the product." Dkt. No. 17008, at 14 (quoting Wis. Stat. § 895.047(1)(a)).

2. <u>Consumer Expectations Remain a Relevant Factor in Determining Product Defectiveness.</u>

Bard's discussion of the role of consumer expectations in interpreting Wisconsin's product liability statute is incomplete. Prior to the passage of the product liability statute in 2011, Wisconsin utilized the consumer expectation test (as opposed to the risk/benefit analysis). *See, In re Zimmer Nexgen Knee Implant Products Liab. Litig.*, 218 F. Supp. 3d

[2] The filter in *Quintana v. B. Braun Med. Inc.*, No. 17-cv-06614, 2018 WL 3559091 (S.D.N.Y. July 24, 2018), cited by Bard (Trial Br. at 4), was a permanent, and not optional, filter.

[3] *See also* Dkt. No. 12805, at 6 ("The evidence in this case suggests, however, that the G2 X and Eclipse filters were designed to be permanent filters, as was the SNF, and that Ms. Hyde's filter would have remained in place if it had not fractured. Whether the retrievability of the G2X and Eclipse made them sufficiently unlike the SNF to disqualify the SNF as a reasonable alternative design is a question for the jury to decide.").

700, 723 (N.D. Ill. 2016), *aff'd sub nom. In re Zimmer, NexGen Knee Implant Products Liab. Litig.*, 884 F.3d 746 (7th Cir. 2018) (citing *Green v. Smith & Nephew AHP, Inc.*, 245 Wis.2d 772, 826, 629 N.W.2d 727, 752 (2001)) (defining the test as, "if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer."). Since the enactment of the 2011 product liability statute, the consumer expectation test has not been rejected by Wisconsin courts, and Bard's suggestion that courts have endorsed any intent "to exorcise consumer expectations entirely from Wisconsin's law," Trial Br., at 8, is an overreach. Even the *Zimmer* case, quoted at length by Bard, agreed that a consumer's expectation remains at least one factor to consider. *In re Zimmer*, 218 F. Supp. at, 723. Following the *Janusz* decision, *supra*, any case that is not inconsistent with statutory law remains authoritative. This Court also indicated that the consumer expectations test remains a fact to consider in determining whether the failure to adopt a proposed alternative design renders a product not reasonably safe. *See* Dkt. No. 12507, at 5-6.

In passing the 2011 product liability statute, the Wisconsin legislature adopted the Restatement (Third) of Torts language in the statute. However, the legislature did not incorporate any of the comments to the Restatement (Third) in the language of the statute. Nor is there any Wisconsin case law that expressly adopts the comments. Any suggestion by Defendants that this Court should be a pioneer in adopting these comments (and thereby changing Wisconsin tort law) is inappropriate. This Court has already rejected that suggestion in declining to offer several jury instructions drawn from Restatement comments in the *Hyde* trial. *See* Dkt. Nos. 12438 (Proposed Jury Instructions), at 46-48; 12824 (Final Jury Instructions).

Even if the Court finds that the Restatement (Third) comments apply, while the consumer expectation test is no longer part of the Wisconsin statute, the comments to the Restatement indicate that the test may still be considered:

> The Restatement (Third) of Torts indicates that the consumer contemplation test may remain relevant even in some design defect cases. Comment g to sec. 2 of the Restatement (Third)

> suggests that "although consumer expectations do not constitute an independent standard for judging the defectiveness of product designs, they may substantially influence or even be ultimately determinative on risk-utility balancing in judging whether the omission of a proposed alternative design renders the product not reasonably safe."

3. The "Inherent Characteristic" Defense Is Not Available to Bard.

Wis. Stat. § 895.047(3)(d) provides, "[t]he court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product." Bard argues that an "inherent characteristic" of the filter that injured Mrs. Tinlin is a risk of fracture. Trial Br. at 9.

As an initial matter, the statute provides that it is for "the court" to decide whether to "dismiss the claimant's action" if this defense applies. Wis. Stat. § 895.047(3)(d). Bard did not move for summary judgment on this issue, or ask for dismissal on this basis. Notably, the only case cited by Bard to interpret this provision of the statute, *Hall v. Boston Sci. Corp.*, No. 2:12-cv-8186, 2015 WL 874760 (S.D. W. Va. Feb. 27, 2015), was a decision on summary judgment.

Bard acknowledges a dearth of Wisconsin law applying this defense, but links the statutory language to the pre-2011 case of *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 743 N.W.2d 159, 162 (2007), a lead paint case. Because *Godoy* was decided before the statute was amended, it is uncertain if its definitions of common law defenses are applicable. Regardless, the retrieval option of the Recovery filter is not an ingredient, as in *Godoy* (lead in lead in paint) or *Hall* (polypropylene in polypropylene mesh slings), whose absence would make the product a "different product." Trial Br. at 9 (quoting *Godoy*, 768 N.W.2d at 684). The Recovery can be considered as much a permanent device as an optional device; in fact, its similarity to its permanent predecessors is the very reason Bard was able to use the 510(k) application process instead of the more rigorous PMA process to seek clearance of the product. If the device can be used both permanently and temporarily, it cannot be logically argued that one or

the other is an ingredient that "make[s] the product something else." *Godoy*, 743 N.W.2d at 231.

Additionally, filter fracture is not an inherent characteristic – like the sharpness of a knife – that would be known to the ordinary consumer. Filter fracture can be prevented or limited by alternative designs such as those proposed by Dr. McMeeking. Bard failed to inform "the ordinary consumer" (whether that is the patient or the doctor) of its failure to test and design away the increased risks of perforation, migration and fracture.

B. Negligent Design

In addition to her strict liability claim for design defect, plaintiff also asserts a negligent design defect claim under Wisconsin common law. There is a degree of overlap between these two claims. *See Below v. Yokohama Tire Corp*., 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017) (holding that strict liability and negligent design defect claims are similar because "the reasonableness of a product's design turns essentially on whether the seller could have come up with a less dangerous design…[T]he state of the art (what the industry feasibly could have done) at the time of the design or manufacture is relevant to the jury's determination of negligence. [T]he jury can make the determination whether the manufacturer reasonably and economically could have chosen an alternative course of conduct.") (internal quotation marks and citation omitted)).

"To succeed on this claim, plaintiffs must prove: (1) the existence of a duty of care on the part of the defendant, (2) a breach of that duty of care, (3) a causal connection between the defendant's breach of the duty of care and the plaintiff's injury, and (4) actual loss or damage resulting from the [breach]." *Kilty v. Weyerhaeuser Company,* No. 16-cv-726 WMC, 2018 WL 2464470 at *3-4 (W.D. Wis. June 1, 2018). Notwithstanding the overlap between strict liability and negligent design defect claims, the focus of a negligent design defect claim is on the defendant's conduct, and a plaintiff bringing a negligent design defect claim is not required to show that the product at issue is unreasonably dangerous. *See Morden v. Cont'l AG*, 611 N.W.2d 659, 675 (Wis. 2000) (cited by Bard in Trial Br., at 10 & 11).

C. Failure to Warn

1. Wisconsin Has Not Adopted the Learned Intermediary Doctrine.

This Court has repeatedly recognized that the Wisconsin Supreme Court has not ruled on the applicability of the learned intermediary doctrine in Wisconsin, and recognized a split of authority among federal courts applying Wisconsin law. *See* Dkt. No. 17008, at 5 n.3; s*ee also* Dkt. No. 12007, at 14 n.6. Another Court overseeing multidistrict litigation against Bard regarding other medical devices has come to the same conclusion. *Rodenkirch-Kleindl v. C.R. Bard, Inc*., No. 2:13-CV-26026, 2016 WL 7116144, at *3 (S.D. W. Va. Dec. 6, 2016). Other Courts have declined to apply the doctrine. "The court need not and will not apply the 'learned intermediary' doctrine in this case. To echo our sister court in the Western District of Wisconsin, 'this court will not create Wisconsin law without some indication that the state's highest court would apply the doctrine if given the opportunity to do so.'" *Forst v. SmithKline Beecham Corp*., 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (citing *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006)).

2. Failure to Warn and Causation

Plaintiffs agree that a failure to warn claim includes a causation element. As this Court recognized, there are multiple avenues available to a medical device manufacturer like Bard to convey warnings to physicians and patients. *See* Dkt. No. 17008, at 5. A plaintiff may still show that a different warning would have changed a doctor's decision even if there is evidence that a doctor did not rely on the information that a defendant did make available. *See Stevens v. Stryker Corp.*, No. 12-cv-63, 2013 WL 12109101, at *6 (W.D. Wis. May 9, 2013).

D. Bard's Failure to Take Post-Sale Remedial Actions

Plaintiffs' failure to warn claim includes Bard's breach of its duty to provide adequate and proper warnings after it began selling the Recovery filter and discovered the

risks and dangers it posed to patients like Ms. Tinlin.[4] Bard's failure to take post-sale remedial action is also relevant to Plaintiffs' claim for punitive damages.

Wisconsin law recognized a manufacturer's post-sale duty to remediate as far back as 1979. *See Kozlowski v. John E. Smith's Sons Co.*, 275 N.W.2d 915, 923-24 (Wis. 1979). While that case pre-dates the enactment of the 2011 product liability statute, Courts have cited the decision favorably since then. For example, in *Bushmaker v. A.W. Chesterton Co.*, No. 09–cv–726–SLC, 2013 WL 11079371, at *6 (W.D. Wis. Mar. 1, 2013), the court examined a case where the plaintiff in an asbestos case argued "that once defendant learned that asbestos-containing products were hazardous, it had a duty to recall its products or to provide warnings about the danger." The *Bushmaker* court cited to section 10 the Restatement (Third) of Torts[5] and found "that in order for a duty to warn, post-sale, to exist, the plaintiff must have some evidence of the sort presented in *Sharp*, namely that it was both practically and economically feasible for the defendant to have provided warnings and that any warnings would have been effective in reaching the users of its products." *Id.* at *8.

The *Bushmaker* court also discussed the applicability of another pre-2011 case:

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[4] Bard also indicates that it intends to offer evidence on its "post-market activities" to support its argument that it "acted reasonably for purposes of the negligent design claim." Trial Br. at 11.

[5] The Restatement (Third), then explains that a reasonable person would issue such a warning if:

> (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
>
> (2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
>
> (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
>
> (4) the risk of harm is sufficiently great to justify the burden of providing a warning.

Bushmaker, 2013 WL 11079371, at *7.

Sharp ex rel. Gordon v. Case Corp., 595 N.W.2d 380 (Wis. 1999) and summarized its relevance to the punitive damages claim as follows:

> In *Sharp*, the plaintiff's arms were amputated when a tractor's power take-off (PTO) shaft engaged without warning as he attempted to clear hay from a baler powered by the PTO….
>
> Notably, the case was submitted to the jury on the post-sale failure to warn theory even though there appears to have been no evidence that Case had developed a safety device in response to the problems reported about its tractor's PTO lever. On the other hand the defendant did not challenge the propriety of the special verdict question on appeal, so we don't know whether the viability of a post-sale failure to warn theory was ever in dispute. That said, the court did mention Case's failure to take "adequate remedial procedures such as product recalls or post-sale warnings," as evidence upon which a jury could make a finding of punitive damages. *Id*. at 23. If, as defendant argues here, a defendant cannot be liable at all for a post-sale failure to warn, then it would follow that it would be improper to consider evidence of such conduct in the punitive damages assessment. Accordingly, *Sharp* indicates that *Kozlowski* 's holding is limited to the failure-to-warn-of-safety-improvements scenario and that a manufacturer may in other instances have a post-sale duty to warn.

Bushmaker, 2013 WL 11079371, at *7.

Once patients started dying from device failures, Bard engaged in a concerted effort to hide any potential knowledge of design problems with device from consumers and its own sales force. To save money and to avoid damage to their image Bard failed to withdraw the Recovery filter from the market even once the successor device, the G2, was cleared for sale, and took no steps to warn doctors of the dangers that Bard itself knew were associated with the Recovery filter.

RESPECTFULLY SUBMITTED this 23rd day of April, 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of April, 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine